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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	7

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 10/084,518	Applicant(s) SELKON, JOE B.	
	Examiner JOHN D PAK	Art Unit 1616	

-- The MAILING DATE f this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *26-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-34 are pending in this application.

Applicant's election without traverse of the invention of Group I, claims 1-25 and 34, in Paper No. 6 (8/6/03) is acknowledged. Accordingly, claims 26-33 are withdrawn from further consideration as being directed to non-elected invention.

Claims 1-25 and 34 will presently be examined.

Claims 1-25 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All claims read on "super-oxidized water based on hypochlorous acid." This term is unclear and indefinite. It is not clear that there are definite metes and bounds to said term. Applicant asserts in the specification (paragraph [0003] that this is a known term in the art. Applicant discloses several products that may fall within its scope (paragraphs [0004] to [0010]. However, what applicant does not disclose is what exactly are the metes and bounds of said term. It is not sufficient that the term is known and there are known examples. The term can be a vague term without a standard accepted meaning with clear boundaries as to its contents or makeup. For example, in China, the medicinal substance "Ai Ling No. 1" was used for many decades and researchers recognized the term, but its composition content fluctuated over time and various research teams used different compositional ingredients. Hence, just because a term is known does not mean that it can be used in a patent claim without indefiniteness problems.

The question is, what is the degree of "oxidized" the water must have, and what are the contents of the "super-oxidized" water that make it fall within or outside the scope of the claimed invention; also, are the requirements of the starting water prior to electrochemical treatment. Applicant has not established that the state of the art is such that the term can only mean one thing that is definable as to its metes and bounds. Until such evidence is submitted, it is the Examiner's position that "super-oxidized water based on hypochlorous acid" is unclear and indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-7, 9-11, 14-15, 17-21, 23-25 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Bakhir et al. (US 5,427,667).

Bakhir et al. explicitly disclose anolyte of water that has gone through electrochemical treatment that has "active chlorine salts" to kill "entirely all microorganisms" (see Examples 2 and 3 on columns 9-10, see in particular Table 2 on columns 9-10; column 10, lines 46-50). Source water contained 0.5 g/l, 1.5 g/l or 3 g/l of minerals (this qualifies the water as "saline," which has a broad meaning that encompasses all salt solutions). Specific pHs of 4.2, 6.4 and 7.0 are disclosed (Table 2 on columns 9-10). Redox potential of 1000 is explicitly disclosed (Table 2)[1]. 99.9% kill in 1.0 to 1.5 seconds is disclosed (column 11, lines 5-6).

Although the cited reference does not expressly state the disclosure in the precise language used by applicant in the instant claims, it is determined that the reference nonetheless discloses the same composition.

The term "super-oxidized water based on hypochlorous acid" is met because applicant's claim 14 shows that such a substance can be obtained by electrochemical treatment of a saline solution. Bakhir's composition is obtained by electrochemical treatment of a mineralized solution, which is a saline, and a highly microbicidal active chlorine mix is obtained. Even though hypochlorous acid is not expressly disclosed, the same must necessarily be present in bakhir's composition since the same process was used. In the alternative, the language "based on hypochlorous acid" is broad enough to

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[1] Although the redox potential of 1000 was disclosed without units, one skilled in the art of electrolyzed water would immediately recognize the unit as being the standard mv, particularly since the source water is from such dilute mineralization as 0.5-3 g/l.

encompass the disclosed active chlorine species that are produced in Bakhir's composition.

Claim 1 is directed to a medicament for open wounds. Given that Bakhir's composition has the same pH, the same redox potential (indication of concentration of oxychlorine species, etc.), has microbicidal properties, and is safe enough to drink, it is the determination of the Examiner that Bakhir's composition would be capable of functioning as claimed by applicant since wound treatments typically require microbicidal treatments. Claim 17 is met for the same reasons.

Claims 11 and 25 recite a biocide rate (D Value) of approximately 1 log reduction unit of bacillus subtilis spores in less than 1 minute with a 9:1 super-oxidized water:innoculum mix. It is the Examiner's position that such activity would have necessarily been present in Bakhir's composition. The reason is that Bakhir's composition is the same in all other respects. Electrolyzed water contains oxychlorine species, and that is the source of its microbicidal activity. Here, Bakhir's composition has the same pH range, the same redox potential and the same method of making. Therefore, the final product must be the same, and it must have the same activity. It is impossible that the PTO can verify every creative way of measuring a prior art substance. If that were the standard of nonobviousness or novelty, all that a subsequent applicant would need to do is to measure a prior art composition in a new way, with some new parameter. Clearly, such a result is unworkable. When, as here, the prior art appears to be the same as applicant's composition, the burden shifts to

applicant to show that the prior art composition does not in fact possess the properties or parameters that are claimed.

Claim 15 requires that the pH be adjusted by using an alkaline output from the electrochemical cell. Such technique is taught by Bakhir et al. – see column 9, lines 40-50. By having the valves not fully closed, mixing of the anolyte and catholyte is obtained and the pH is thus adjusted.

Claim 34 is directed to a hydrobath preparation for treating ulcers or other open wounds. Given that Bakhir's composition has the same pH, the same redox potential (indication of concentration of oxychlorine species, etc.), has microbicidal properties, and is safe enough to drink, it is the determination of the Examiner that Bakhir's composition would be capable of functioning as claimed by applicant since wound treatments typically require microbicidal treatments. The term "hydrobath" does not further distinguish over Bakhir's disclosure because it discloses large amounts of water that could be used in a hydrobath.

For these reasons, the claims are anticipated. See MPEP 2112, 2112.01.

Claims 8 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakhir et al.

As discussed above, Bakhir et al. explicitly disclose anolyte of water that has gone through electrochemical treatment that has "active chlorine salts" to kill "entirely all microorganisms" (see Examples 2 and 3 on columns 9-10, see in particular Table 2 on columns 9-10; column 10, lines 46-50). Source water contained 0.5 g/l, 1.5 g/l or 3 g/l

of minerals (this qualifies the water as "saline," which has a broad meaning that encompasses all salt solutions). Specific pHs of 3.5, 4.2, 6.4 and 7.0 are disclosed (Table 2 on columns 9-10). Redox potential of 1000 is explicitly disclosed (Table 2). 99.9% kill in 1.0 to 1.5 seconds is disclosed (column 11, lines 5-6).

The difference between the claimed invention and the cited reference is that pH 5.4 is not specifically exemplified. However, the pH range covering such a value is disclosed. Further, any specific pH would have been obtained by adjusting the mix of anolyte and catholyte, mineralization, and ORP. The motivation to do so would have come from the need to tailor the composition to the microbial challenge particular to the situation. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to adjust the pH to 5.4 with the expectation that the electrochemically treated water would provide advantageous microbicidal properties.

Claims 1-2, 4-7, 14-21 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Chemical Abstracts 127:39419.

Chemical Abstracts 127:39419 explicitly discloses solutions that contain chlorides and phosphates as pH regulators. pH is adjusted to 6-7.5. The chlorides produce "HClO-sterilized water." The solutions are subjected to "nondiaphragm electrolysis," which means that the anolyte and catholyte are mixed.

The term "super-oxidized water based on hypochlorous acid" is met because applicant's claim 14 shows that such a substance can be obtained by electrochemical

treatment of a saline solution. The prior art composition is obtained by electrolysis of a chloride solution, which is a saline, and a HClO-sterilized water is obtained. Even though hypochlorous acid is not expressly disclosed, the same must necessarily be present in the prior art composition since the same process was used. In the alternative, the language "based on hypochlorous acid" is broad enough to encompass the disclosed active chlorine species that are produced in the prior art composition.

Claim 1 is directed to a medicament for open wounds. Given that the prior art composition was made by the same process, has the same pH, and has microbicidal properties, it is the determination of the Examiner that the prior art composition would be capable of functioning as claimed by applicant since wound treatments typically require microbicidal treatments. Claim 17 is met for the same reasons.

Claim 15 requires that the pH be adjusted by using an alkaline output from the electrochemical cell. Such technique is taught by the cited reference – by using nondiaphragm electrolysis, mixing of the anolyte and catholyte is obtained and the pH is thus adjusted.

Claim 34 is directed to a hydrobath preparation for treating ulcers or other open wounds. Given that the prior art composition was obtained from the same electrochemical process, has the same pH, and has microbicidal properties, it is the determination of the Examiner that the prior art composition would be capable of functioning as claimed by applicant since wound treatments typically require microbicidal treatments. The term "hydrobath" does not further distinguish over the

cited disclosure because it discloses sufficient amounts of water that could be used in a hydrobath.

For these reasons, the claims are anticipated. See MPEP 2112, 2112.01.

Claims 1, 3, 12-13, 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Rogozinski (US 6,333,054).

Rogozinski explicitly discloses a hypochlorous acid based hydrogel that was subjected to electrolysis, which is useful for treating wounds and infections (see claims 1, 8, 10-16).

It is noted that Rogozinski does not explicitly disclose dilution to the extent that cell proliferation is promoted or not inhibited. However, Rogozinski's hydrogel is for treating topical infections such as wounds. Therefore, for such utility to be possible, cell proliferation would not have been inhibited, and wound treatment disinfecting utility would have promoted cell proliferation. Hence, the "dilution to an extent" feature is met. The claims are thereby anticipated.

It is noted that applicant has not perfected the foreign priority claim. This reference is therefore applicable.

Claims 1, 3, 12-13, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chemical Abstracts 124:66697.

Chemical Abstracts 124:66697 explicitly discloses electrolyzed water combined with a thickening agent (e.g. hydroxypropyl cellulose M) for use as bactericides, e.g. for treating wounds after surgery.

As discussed previously in this Office Action, it is known that electrolyzed water has microbicidal properties and contains various oxychlorine species; and that is sufficient to meet the "super-oxidized water based on hypochlorous acid" feature.

It is noted that the cited reference does not explicitly disclose dilution to the extent that cell proliferation is promoted or not inhibited. However, the combination of hydroxypropyl cellulose + electrolyzed water is for bactericidally treating wounds. Therefore, for such utility to be possible, cell proliferation would not have been inhibited, and wound treatment disinfecting utility would have promoted cell proliferation. Hence, the "dilution to an extent" feature is met. As for the gel feature, the hycroxypropyl cellulose thickening agent would have produced a gel-like composition. The claims are thereby anticipated.

For these reasons, all claims must be refused.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN D PAK whose telephone number is (703)308-4538. The examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600